

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

IN RE: BRIMONIDINE PATENT
LITIGATION

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) C.A. No. 07-MD-01866-GMS
)

APOTEX'S OPENING CLAIM CONSTRUCTION BRIEF

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867652 / 31920 (MDL)

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INTRODUCTION

Pursuant to the Revised Proposed Scheduling Order dated May 30, 2008 (D.I. 45), drafted in accordance with the March 26, 2008 Telephone Conference with the Court, Defendants Apotex, Inc. and Apotex, Corp. (collectively, "Apotex") respectfully submit this Opening Claim Construction Brief with respect to its proposed claim constructions of U.S. Patent Nos. 5,424,078 ("the '078 patent"), 6,562,873 ("the '873 patent"), 6,627,210 ("the '210 patent"), 6,673,337 ("the '337 patent"), and 6,641,834 ("the '834 patent").

Significantly, in an ongoing effort to narrow issues presented to the Court, Allergan, Inc. ("Allergan"), Apotex, and MDL defendants Exela PharmSci, Inc., Exela Pharm Sci Pvt., Ltd., Paddock Laboratories, Inc., and PharmaForce Inc. (collectively "the Exela Defendants") have reached agreement on most of the construction of terms previously identified as contested in the Joint Claim Charts filed with the Court on May 16, 2008. (D.I. 42.) As a result, Allergan and Apotex have no disputes as to claim construction for any of the patents. As explained below, although Apotex does not understand the differences to be substantively significant, the Exela Defendants have proffered their own constructions for some of the terms in the '834 patent. The parties' Revised Joint Claim Charts, which include the agreed constructions of Allergan, Apotex, and the Exela Defendants, and the separate and unchanged constructions of the Exela Defendants on the '834 patent, is being filed today. (D.I. 46.)¹

¹ Allergan has asserted each of the '078, '873, '210, '337, and '834 patents against Apotex. The '834 patent is the only patent currently being asserted against the Exela Defendants.

ARGUMENT

I. Apotex and Allergan Agree on the Construction of All Claims

As is clear from a review of the Revised Joint Claim Charts, Apotex and Allergan agree an overwhelming majority of claim terms of the '078, '873, '210, '337, and '834 patents should be afforded their ordinary and customary meaning. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) ("In some cases, the ordinary meaning of claim language as understood by a person of ordinary skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.") To the extent the meaning of the claim terms of any patent require clarification, Apotex and Allergan have agreed on proposed constructions for each patent claim. The parties' Revised Joint Claim Chart incorporating Apotex and Allergan's agreed-upon claim construction is being filed concurrently with the Court.

II. Apotex's and the Exela Defendants' Constructions Do Not Appear to be Materially Different

The Exela Defendants have offered their own proposed constructions and guidance to the Court with respect to certain claims of the '834 patent. In all cases, it is unclear to Apotex that the Exela Defendants' specific constructions materially differ from the constructions offered by Apotex.² Apotex believes its proposed constructions are preferable, however, as they are more consistent with the language used in the claims themselves.

For example, Apotex and the Exela Defendants offer the following different constructions of claim 1:

² The following claims asserted against the Exela Defendants are not being asserted against Apotex, and Apotex takes no position on the proposed construction of these claims by the Allergan or the Exela Defendants: claims 8, 9, 17 and 18. Additionally, claims 5, 7, 14, 15, 16 and 22 are being asserted against Apotex, but not the Exela Defendants. As noted previously, Apotex and Allergan have proposed agreed-upon constructions of each of these claims.

| Asserted Claim of '834 Patent | Apotex's Proposed Construction | Exela's Proposed Construction |
|--|---|---|
| Claim 1 | | |
| 1. A therapeutically effective aqueous ophthalmic composition comprising: up to about 0.15% (w/v) of 5-bromo-6-(2-imidazolylamino) quinoxaline tartrate, | The claim requires a therapeutically effective aqueous ophthalmic composition. The claimed composition comprises up to approximately 0.15% brimonidine tartrate. | A water-based formulation containing between 0% and about 0.15% (w/v) of brimonidine tartrate for ophthalmic administration that is demonstrated to provide a therapeutic benefit to a patient to whom the formulation is administered. |
| the composition having a pH of about 7.0 or greater, | The claimed composition has a pH of approximately 7.0 or greater. | The therapeutically effective formulation referred to above has a pH of 7.0 or greater within measurement tolerances. In no event can the claim cover a formulation having a pH of 6.8 or below. |
| and the 5-bromo-6-(2-imidazolylamino) quinoxaline tartrate being soluble in the composition at about 21° C. | Agreed-upon construction - The brimonidine tartrate is soluble in the composition at approximately 21° C. | |

The two constructions do not appear materially different in most respects. For example, Apotex's position is the ordinary and customary meaning of "therapeutically effective" is self-evident. It is unclear the Exela Defendants intend their construction ("a therapeutic benefit to a patient to whom the formulation is administered") to deviate from the customary meaning of the claim itself. Similarly, Apotex's position is the construction of the "aqueous ... composition" claim limitation of claim 1 "involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips*, 415 F.3d at 1314. The Exela Defendants construe this limitation to mean a "water-based formulation." It is not apparent to Apotex the Exela

Defendants' "water-based formulation" construction is at all different from the widely accepted meaning of the claim terms themselves.

The Exela Defendants also take pains to construe "up to about 0.15% (w/v)" as "between 0% and about 0.15% (w/v)". One skilled in the art would understand the ordinary and customary meaning of "up to about 0.15%" to include a range between "0% and about 15% (w/v)". The Exela Defendants' construction offers nothing more than the ordinary and customary meaning restated in the Exela Defendants' preferred form.

Also, the Exela Defendants do not construe "about" in the limitation "about 15% (w/v)", but carefully construe the term when it appears in the limitation "a pH of about 7.0 or greater." Apotex sees no utility in belaboring the point, however, as this Court has previously construed the term "about" in the '834 patent claims to mean "approximately". *Allergan Inc. v. Alcon Inc.*, No. 04-968 (GMS) (D. Del. July 26, 2005). The Exela Defendants' concede this point in agreeing with Apotex on the construction of "about" in the final limitation of claim 1, as noted above.

Apotex has similarly evaluated the proposed differences between Apotex's and the Exela Defendants' constructions on the remaining common claims asserted against them. Apotex is unable to discern any material difference between the parties' respective positions, largely for the reasons stated above. Since Apotex's constructions are more consistent with the claim language, the specification of the '834 patent and prior rulings of this Court, Apotex respectfully requests the Court adopt its proposed constructions. In the event it becomes apparent following opening briefing the Exela Defendants' are taking a position materially different from the position taken by Apotex, Apotex reserves its right to respond to the Exela Defendants' proposed constructions in its answering brief in support of Apotex's own proposed constructions.

CONCLUSION

Apotex respectfully requests the Court construe the claims according to the agreed-upon constructions of Apotex and Allergan (and the Exela Defendants where applicable) as reflected in the parties' Revised Joint Claim Charts filed with the Court today. (D.I. 46.)

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